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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,826	01/31/2001	John D. Roback	050508-1030	7152
7590 09/20/2005			EXAMINER	
Scott A. Horstemeyer THOMAS, KAYDEN, HORSTEMEYER & RISLEY, L.L.P. 100 Galleria Parkway, N.W., Suite 1750 Atlanta, GA 30339-5948			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/773,826

Applicant(s)

ROBACK ET AL

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,8,9,11 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8,9,11 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on June 27, 2005. Claims 1-4, 6, 8, 9, 11, 25-28 are pending. Claims 12-24 are withdrawn from consideration.

#### *Withdrawal of Rejections from Previous Office Action*

- The anticipation rejection over Yaremko et al is withdrawn in view of Applicants' amendment to recite the particular filter materials being used in the analysis system. Likewise, the obviousness rejection over Yaremko et al in view of Takahashi et al and the obviousness rejections over Yaremko et al in view of Takahashi et al and Franciskovich et al are withdrawn.
- The obviousness rejection over Yaremko et al in view of Takahashi et al and Datar is withdrawn in view of Applicants' amendment to incorporate a particular pore size for the filter material.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2-6, 8, 11 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US patent 5,308,990 to Takahashi et al and US patent 6,182,834 to Kim et al.

Yaremko et al teach an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606). The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers, as recited in claims 1 and 25 (col. 5, lines 39-

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42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filter is made of either beads or a porous gel material, as recited in claims 1, 3 and 4. The beads have a size of 10-100 microns, as recited in claim 5. See col. 6, lines 9-32. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims 1, 8, 25 and 27 (col. 13, line 61 – col. 15, line 3). The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claim 11 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises a pipette (402) and a robot arm (404), as recited in claim 1 (col. 13, lines 1-12). With respect to the washer recited in claim 2, Yaremko et al teach that washers (406, 410) contain liquids for rinsing or cleaning (col. 13, lines 23-28).

Yaremko et al differs from the instant invention in that it teaches a camera to image the analysis results, whereas Applicants claim the use of flow cytometer.

Takahashi et al teach that flow cytometers can be used in immunological measurement methods to determine antigen-antibody reactions and agglutination from the antigen-antibody reactions (col. 1, lines 37-53). It would have been obvious to one of ordinary skill in the art to substitute the camera system of Yaremko et al for a flow cytometer to provide a means to determine antigen-antibody interactions and agglutination in immunological assays.

Yaremko et al further differ from the instant invention in that the particular filter materials recited by Applicants are not taught.

Kim et al teaches a means for filtering white blood cells that offers good recovery of platelets and red blood cells. Kim et al teaches using a non-woven filter material, such as polyester, polyamide, and cellulosic materials. The filter materials have a pore size of not more than 3 microns (col. 3, lines 52-60). It would have been obvious to one of ordinary skill in the art to use the polyester or cellulose materials as

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filters in the device of Yaremko et al due to the teachings in Kim et al that these materials having a pore size of 3 microns provide excellent filtration of white blood cells with good recovery of platelets and red blood cells. See col. 1, lines 5-15.

2. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al, Takahashi et al and Kim et al, as applied above, and further in view of US Patent 5,603,899 to Franciskovich et al.

The disclosures of Yaremko et al and Takahashi et al are described above. Neither Yaremko et al nor Takahashi et al teach a vacuum system for separating the sample.

Franciskovich et al teach an apparatus for separating samples into their constituents. The reference teaches that both centrifuges and vacuums provide good means for separating multiple samples into their base constituents simultaneously. See col. 2, lines 25-31. Thus, it would have been obvious to substitute the centrifuge assembly of Yaremko et al with a vacuum assembly as disclosed by Franciskovich et al to allow simultaneous separation of multiple samples and thus increase the sample processing time.

#### *Response to Arguments*

3. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MONIQUE T. COLE  
PRIMARY EXAMINER